REMARKS

Applicants submit this Request for Reconsideration After Final in reply to the Office Action mailed on April 18, 2005. Claims 59-62, 64, 66-68, and 83-91 have been previously presented for examination. Of these claims, claims 59-62, 64, 66-68, and 83-84 were examined. Claim 83 is the sole independent claim.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication of the allowability of claims 59-62, 68, and 84. However, because Applicants believe independent claim 83, from which claims 59-62, 68, and 84 depend, is patentable over the cited reference, Applicants have not rewritten claims 59-62, 68, and 84 into independent form at this time.

On pages 2-3 of the Office Action, claims 64, 66, 67, and 83 were rejected under 35 U.S.C. § 102(b) as being anticipated by Alferness (U.S. Patent No. 5,702,343). The Examiner made the rejections final. Applicants respectfully traverse these rejections because Alferness fails to teach each and every element of independent claim 83.

Independent claim 83 is directed to a method of treating an in situ mitral valve and recites

> positioning a passive device with respect to a heart such that, ***throughout the cardiac cycle***, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve***, wherein the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve***.

(Emphasis added.)

As explained in Applicants' Request for Reconsideration filed on January 5, 2005, Alferness discloses a cardiac reinforcement device (CRD) and method for treating

cardiomyopathy. More specifically, Alferness discloses a device and treatment method that provide reinforcement of the cardiac wall during only diastole by applying the device to the epicardial surface of the heart. *See, e.g.,* Alferness, col. 1, lines 8-14. Alferness explicitly teaches that the disclosed cardiac reinforcement devices do not provide cardiac assistance during systole, in contrast to prior art ventricular assistance devices. *See, e.g.,* Alferness, col. 3, lines 1-5, 11-14, and 33-38. Alferness further teaches that the cardiac reinforcement devices function so as to reduce cardiac dilation and thereby potentially prevent or reduce problems that are associated with such dilation. *See, e.g.,* Alferness, col. 1, lines 25-30, and col. 5, lines 26-44.

Therefore, contrary to the Examiner's assertions otherwise in the Office Action, there are two independent reasons why Alferness fails to teach each and every element of independent claim 83. Specifically, Alferness neither discloses nor suggests, either explicitly or otherwise, that "throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure" or that "the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve," as recited in independent claim 83. Each of these claim limitations and the reasons why Alferness fails to disclose or suggest them, either explicitly or otherwise, will be addressed individually.

I. Alferness does not disclose devices that act "throughout the cardiac cycle"

In the Office Action, the Examiner alleges that the teaching of Alferness to position a cardiac reinforcement jacket device under the parietal pericardium is a teaching of

> [altering] the geometry of the cardiac wall throughout the

> cardiac cycle by virtue of the device thickness shifting the cardiac wall inwardly from the parietal pericardium and the device material (and thickness) altering the dynamic response characteristics of the cardiac wall, the device, and the parietal pericardium in combination.

See Office Action at page 2.

Alferness does not explicitly disclose altering the geometry of the cardiac wall throughout the cardiac cycle, as recited in independent claim 83. To the contrary, as discussed above, Alferness explicitly teaches that the disclosed cardiac reinforcement devices act only during diastole and not during systole to provide cardiac reinforcement. Since Alferness contains no explicit disclosure that the disclosed cardiac reinforcement devices alter the geometry of the cardiac wall throughout the cardiac cycle, it appears the Examiner may be relying on inherency principles to support the rejection based on Alferness. To establish inherency, the Examiner must show that "the missing descriptive matter is *necessarily* present" in the reference. *See* M.P.E.P § 2112, Original Eighth Ed., Aug. 2001, Revision May 2004 (*quoting in re Robertson*, 49 U.S.P.Q. 2d 1949 (Fed. Cir. 1999). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112 (emphasis in original.)

In the present case, the Examiner has not established that Alferness's disclosure of placing a cardiac reinforcement jacket under the parietal pericardium is necessarily a teaching of altering a geometry of heart structure throughout the cardiac cycle, as required by independent claim 83. This is especially true in light of Alferness's explicit disclosure that the disclosed devices act only during diastole and not during systole. For the alleged altering of heart structure geometry throughout the cardiac cycle to

occur, the disclosed cardiac reinforcement device at least would need a thickness sufficient to occupy the space between the heart and the parietal pericardium. However, the possibility exists for a cardiac reinforcement device to have a thickness whereby the device does ***not*** occupy sufficient space between the parietal pericardium and the cardiac wall so as to shift the cardiac wall inwardly or otherwise alter heart structure geometry throughout the cardiac cycle. In this regard, Alferness contains no explicit disclosure in its text regarding the thickness of the device. Since a device without sufficient thickness to occupy the appropriate space may exist, the Examiner has failed to establish inherency.

Notably, the Examiner has provided no evidence to support the assertion that the cardiac reinforcement devices disclosed by Alferness *necessarily* have the thickness required to perform the alleged functions, and instead relies on conclusory assertions. If the Examiner maintains the rejection based on Alferness, Applicants once again request the Examiner to supply documentary evidence supporting the assertions regarding the thickness of the cardiac reinforcement devices and that they necessarily act throughout the cardiac cycle.

Moreover, it is likely that it would be undesirable for the cardiac reinforcement devices disclosed by Alferness to have a thickness large enough to occupy sufficient space between the heart and the parietal pericardium because this could cause excessive compression of the heart in a uniform manner throughout the cardiac cycle. Such uniform, excessive compression could result in tamponade of the heart muscle, which is an undesirable compression of the heart typically caused by blood or fluid accumulation in the space between the myocardium and the pericardium.

In response to the Applicants' prior remarks filed on January 5, 2005, the Examiner alleges that "the configuration or arrangement of the cardiac wall and the parietal pericardium is clearly altered (throughout the cardiac cycle) by the placement of an Alferness cardiac reinforcement device between these two natural structures." *See* Office Action at page 3. As explained above, in order for the Examiner's allegations and assumptions to be true, the Alferness device must *necessarily* have a thickness greater than the space between the pericardium and the myocardium. Alferness does not contain any explicit disclosure regarding the thickness of the disclosed device, and the Examiner has not provided any evidence that any of the embodiments of the Alferness device possesses a thickness larger than the space between the pericardium and the myocardium. Moreover, as set forth above, it is unlikely that the Alferness device possesses a thickness larger than the space between the pericardium and the myocardium, as would be required to alter heart structure throughout the cardiac cycle, because such a thickness could result in excessive, uniform compression of the heart that could lead to undesirable cardiac tamponade.

Furthermore, since the Alferness patent does not contain any explicit textual disclosure regarding the thicknesses of the disclosed devices, the figures of that patent provide the only indication of the size of the disclosed devices. Figure 5 best indicates the device size since it is shown in perspective view relative to a heart. That Figure shows the device thickness to be, for example, much less than a width of a main descending coronary vessel, which typically has a width of about 3-4 mm. In addition, rather than indicating that the device has any appreciable thickness, Figure 5 shows that the device disclosed by Alferness lies essentially flush with heart surface. Thus, it

is likely that the devices disclosed by Alferness are intended to be positioned within the space between the pericardium and the myocardium, in a manner that does not shift the cardiac wall inward from the pericardium or otherwise alter heart structure geometry throughout the cardiac cycle.

Moreover, if the Examiner contends that any alleged altering of the pericardium by the Alferness device meets the claim limitation to "alter geometry of heart structure," Applicants note that the pericardium is not "heart structure." As Alferness recognizes, "[t]he heart is enclosed within a double walled sac known as the pericardium." Col. 2, lines 59-60. Thus, one skilled in the art recognizes that pericardium is something other than the heart.

For at least the above reasons, Alferness fails to disclose or otherwise suggest, either explicitly or otherwise, a method for treating an in situ mitral valve, as recited in claim 83, and the Section 102 rejection based on Alferness should be withdrawn.

II. Alferness does not disclose a "passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve"

As a second independent basis to distinguish claim 83 from Alferness, Alferness does not disclose a "passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve." In the Office Action, the Examiner asserts that column 1, lines 25-30, and column 5, lines 26-44 of Alferness allegedly teach that the cardiac reinforcement device of Alferness draws together leaflets of the in situ valve to promote closure of said valve. *See* Office Action at page 2. However, the cited passages, as well as the remainder of the disclosure in Alferness, describe a device that constrains cardiac expansion solely during diastole so as to prevent enlargement

(*i.e.,* dilation) of the heart. These passages do not disclose or otherwise suggest a device that acts on the valve or draws together leaflets to close the valve. At most, Alferness may be interpreted to teach that use of the disclosed cardiac reinforcement devices for constraining cardiac expansion during diastole and preventing cardiac dilation may prevent the naturally occurring consequences of valvular leakage. This, however, is not a teaching of a device that explicitly or inherently "draws together leaflets of the in situ valve to promote closure of the in situ valve."

In response to the Applicants' remarks in the Request for Reconsideration filed on January 5, 2005, the Examiner alleges that Alferness, by disclosing that "[r]educed cardiac dilation can cause reduction in the problems associated with cardiac dilation such as arrhythmias and valvular leakage" and by disclosing embodiments where "the predetermined size can be adjusted for size reduction as the cardiac size is reduced," discloses a method of treating an in situ mitral valve comprising a "passive device [that] draws together leaflets of the in situ valve to promote closure of the in situ valve," as required by independent claim 83. The Examiner also places the burden on "[t]he Applicant [to] explain how the Alferness device reduces valvular leakage, if not by drawing together leaflets of the in situ valve." *See* Office Action at page 3.

Although Applicants do not necessarily agree with the Examiner's allegations, Applicants will explain further that the devices disclosed by Alferness do not draw together the leaflets of the mitral valve. Alferness merely discloses a device that constrains cardiac expansion, which can provide reduced cardiac dilation. The reduction in ventricle size over time may help to facilitate the heart's natural ability to assuage some of the problems associated with cardiac dilation, such as arrhythmias

and valvular leakage. In other words, any reduction in valvular leakage in a heart equipped with a device disclosed by Alferness stems from a fortuitous, natural response of the heart to being constrained against excessive cardiac expansion, not from the Alferness device acting in a way to draw the leaflets together.

Furthermore, as discussed above, Alferness explicitly teaches that the disclosed devices solely limit the outward expansion of the heart wall during diastolic chamber filling. *See, e.g.,* col. 2, lines 63-65. Indeed, Alferness explicitly states that "[t]he present invention is directed to reinforcement of the heart wall during diastolic filling of a chamber of the heart." *See, e.g.,* col. 2, lines 47-49. Additionally, as also noted above, Alferness explicitly states that unlike "known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole." *See, e.g.,* col. 3, lines 1-4.

"Diastolic filling" and "diastole" refer to the filling of the left ventricle with blood from the left atrium. During this time, the mitral valve is in an open configuration, so as to allow blood to exit the left atrium and enter the left ventricle. In contrast, "systole" refers to the contraction of the left ventricular muscle wall to expel blood from the left ventricle, through the aortic valve, and into the body. During this function, the mitral valve is in a closed configuration, so as to prevent backflow of blood into the left atrium.

Thus, since Alferness discloses devices that provide cardiac reinforcement only during diastole, a time when the mitral valve is naturally open, it is counterintuitive for the Alferness devices to "draw together leaflets of [an] in situ valve to promote closure of the in situ valve" during diastolic filling, as alleged by the Examiner. *Assuming arguendo* that the Alferness devices function as alleged by the Examiner, the devices

would urge the mitral valve to close only when the valve is naturally designed to be open, which may hinder the natural functions of the heart.

For at least the above reasons, therefore, Alferness fails to disclose or otherwise suggest, either explicitly or otherwise, a method for treating an in situ mitral valve, as recited in claim 83, and the Section 102 rejection based on Alferness should be withdrawn.

Claims 59-62, 64, 66-68, and 84 depend from claim 83 and are therefore allowable for at least the same reasons claim 83 is allowable. In addition, as recognized by the Examiner, at least some of those dependent claims recite unique features and combinations that are neither taught nor suggested by the cited art, and thus, at least some are also separately patentable.

Applicants respectfully request that this Request for Reconsideration After Final under 37 C.F.R. § 1.116 be considered by the Examiner, placing claims 59-62, 64, 66-68, 83, and 84 in condition for allowance. There are no proposed amendments, and thus the application does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships were earlier claimed in the claims as examined. Therefore, this Request for Reconsideration After Final should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the Final Office Action by the Examiner presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the entry of this Request for Reconsideration After Final would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

In view of the foregoing remarks, Applicants submit that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the consideration of this Request for Reconsideration After Final, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Final Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Final Office Action.

In discussing the claims in this Request for Reconsideration After Final, Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Request for Reconsideration After Final and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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